

## IN THE CLAIMS

### *I. Substitution of Claims*

Claims 1-4 and 7-22 now pending in this application are listed below. Please cancel claim 13. Please substitute pending claims 1, 3-4, 7-8, 10 and 12 with the corresponding amended claims 1, 3-4, 7-8, 10 and 12 as shown below:

1. (Amended) A stable, aerosolizable composition that is pharmaceutically suitable for rapid bronchial delivery to a lung of a subject, the composition comprising a therapeutically effective amount of delta-9-tetrahydrocannabinol in a pharmaceutically-acceptable semiaqueous solvent comprising volumetric ratios of about 10-70 parts of ethanol, about 10-30 parts of water and greater than about 20-80 parts of propylene glycol having a combined total of 100, provided that:

- D*  
*Sub*  
*E1*
- (i) upon aerosolization the composition has a mean mass median aerodynamic diameter in the range from about 1 up to about 10  $\mu$ M; and
  - (ii) the ratio of the ethanol, water and propylene glycol produces a stable clear solution near the solubility point of the delta-9-tetrahydrocannabinol such that upon administration to the lung, the partitioning of the delta-9-tetrahydrocannabinol from the solvent is enhanced so as to reach the bloodstream.

2. A composition as defined in Claim 1 wherein the amount of delta-9-tetrahydrocannabinol comprises from about 0.1 to about 200 mg delta-9-tetrahydrocannabinol/mL of the solvent.

D<sup>2</sup>  
Sub F1  
Cont

3. (Amended) A composition as defined in Claim 2 wherein the amount of delta-9- tetrahydrocannabinol comprises from about 0.1 to 25 mg delta-9- tetrahydrocannabinol/mL of the solvent.

4. (Amended) A composition as defined in Claim 2 wherein the amount of delta-9- tetrahydrocannabinol comprises about 50 mg delta-9-tetrahydrocannabinol/mL of the solvent.

Sub E2  
D<sup>3</sup>

7. (Amended) A composition as defined in Claim 1 wherein the volumetric ratios of ethanol : water : propylene glycol are selected from those in the range of from about 10 – 70 : about 10 : greater than 20 – 80 respectively, having a combined total of 100.

D<sup>4</sup>  
Sub F1  
Cont

8. (Amended) A composition as defined in Claim 7 wherein the volumetric ratios of ethanol : water : propylene glycol are about 35 : about 10 : about 55, respectively, having a combined total of 100.

9. A sterile and/or preserved sealed unit– or multi-unit dosage form of delta-9-tetrahydrocannabinol comprising a container and a stable composition for rapid delivery by inhalation to the lungs and subsequently to the bloodstream, as defined in Claim 1.

D<sup>5</sup>  
Sub F1  
Cont

10. (Amended) A sterile and/or preserved sealed unit- or multi-unit dosage form as defined in Claim 9 wherein said container comprises Type I Amber Glass

11. The composition of claim 1, wherein the mean mass median aerodynamic diameter is from about 1  $\mu$ M to about 3  $\mu$ M.

D<sup>6</sup>  
Sub F1  
Cont

12. (Amended) The composition of claim 1, wherein the ethanol is replaced with isopropanol.

13. cancelled
14. The composition of claim 1, wherein the amount of delta-9-tetrahydrocannabinol is from about 0.05% to about 15%, by weight, of the composition.
15. The composition of claim 14, wherein the amount of delta-9-tetrahydrocannabinol is from about 0.02% to about 5%, by weight, of the composition.
16. The composition of claim 15, wherein the amount of delta-9-tetrahydrocannabinol is from about 0.1% to about 4%, by weight, of the composition.
17. The composition of claim 1, wherein the amount of delta-9-tetrahydrocannabinol is from about 0.01 mg to about 100 mg per kilogram of body weight of the subject.
18. The composition of claim 17, wherein the amount of delta-9-tetrahydrocannabinol is from about 0.025 mg to about 35 mg per kilogram of body weight of the subject.
19. The composition of claim 18, wherein the amount of delta-9-tetrahydrocannabinol is from about 0.05 mg to about 5 mg per kilogram of body weight of the subject.
20. The composition of claim 1, further comprising an agent selected from the group consisting of an anti-oxidant, surfactant, buffer, pH adjusting agent, bacteriostatic agent, stabilizer, sodium chloride, and preservative.
21. The composition of claim 1, wherein the composition is administered to the subject one to five times a day.
22. The composition of claim 1, wherein the subject is a human.

## ***II. Addition of New Claims***